

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 1-2 and 4-13 are pending in the present application. Claim 1 has been amended. Support for amended claim 1 may be found in the present specification at page 11, line 6 and page 6, line 20. Claims 3 and 14 have been canceled.

In the outstanding Official Action, claim 1 was rejected under 35 USC §112, first paragraph, for allegedly not satisfying the enablement requirement. In imposing the rejection, the Official Action alleged that the solubility of the calcium used in part B was critical or essential to the practice of the invention. However, this rejection is respectfully traversed.

In addressing the enablement requirement, the Official Action cites to *In re Mayhew*, 527 F.2d 1229, 1233, 188 USPQ 356, 358 (CCPA 1976), for the proposition that claims failing to recite a necessary element of an invention fail for lack of an enabling disclosure. There, however, the method claims omitted a step without which the invention as claimed was wholly inoperative. In other words, the claimed method simply would not work and could not produce the desired result. *Amgen v. Hoechst Marion Roussel*, 314 F.3d 1313, 65 USPQ 2d 1385 (Fed. Cir. 2003).

However, as to the present invention, the lack of a recitation directed to the solubility of the calcium does not prevent one skilled in the art from practicing the claimed method. Thus, the lack of a description as to the solubility of the calcium does not render the invention wholly inoperable and therefore does not run a foul of *In re Mayhew*, 527 F.2d at 1233, 188 USPQ at 358.

Nevertheless, in the interest of advancing prosecution, claim 1 has been amended to recite "a solubility range of below 0.5 grams per 100 ml demineralized water at 20°C and pH7". Thus, applicants believe that the rejection has been obviated by the present amendment.

Claim 1 was further rejected under 35 USC §112, first paragraph, for allegedly not satisfying the enablement requirement for reciting "a degree of methoxylation between 2 and 50". The Examiner's attention is respectfully directed to page 9, line 20 in the present specification, wherein "a degree of methoxylation below 50%" is recited. While applicants note that a range between 2 and 50 falls within a degree of methoxylation below 50%, claim 1 has been amended to advance prosecution of the present application. As expressly stated in the present specification, claim 1 now recites "a degree of methoxylation below 50%".

Claims 3 and 14 were also rejected under 35 USC §112, first paragraph.

However, as noted above, claims 3 and 14 have been canceled. Thus, applicants believe that these rejections have been obviated by the present amendment.

Claims 1-13 were rejected under 35 USC §103(a) as allegedly being unpatentable over YAMAGATA et al. This rejection is respectfully traversed.

YAMAGATA et al. are concerned with patients that are weak and undernourished (column 1, line 35). In contrast, the present composition aims to reduce appetite, and is particularly suitable for patients who are overweight or suffering from obesity, i.e., an opposite approach. Applicants believe that the claimed composition differs from the composition described by YAMAGATA et al.

YAMAGATA et al. do not disclose or suggest the claimed calcium component. The composition described in Example 8 of YAMAGATA et al. contains calcium gluconate, which has a solubility of 0.3 gram per 100 ml (see MSDS sheet of calcium gluconate), i.e., above the upper limit of 0.15 grams per 100 ml in claim 1. As a result, YAMAGATA et al. teach away from the claimed invention by stating that certain calcium sources are preferred "because they are highly soluble in clean water" (column 4, lines 8-11).

YAMAGATA et al. further fail to describe a composition containing a combination of (a) pectin and/or alginate, (b) calcium and (c) indigestible oligosaccharides.

YAMAGATA et al. fail to recognize that a composition containing pectin in combination with a calcium salt with low solubility provides a stable liquid composition. Furthermore, YAMAGATA et al. do not address the problem of reduced calcium uptake, which is a consequence of the inclusion of low methoxylated pectin and/or alginate.

Attached is a declaration by Dr. K.M.J. van Laere. The experimental results referred to in the declaration show that oligosaccharides effectively increase the level of bioavailable calcium in LM pectin containing compositions.

In particular, YAMAGATA et al. fail to teach or suggest the inclusion of indigestible oligosaccharides. While the Office Action argues that it would have been obvious to include oligosaccharides in the composition of YAMAGATA to fortify the composition, neither YAMAGATA et al. nor any of the other cited publications provide adequate basis for this statement. In addition, it is noted that claim 1 requires the presence of indigestible oligosaccharides. Thus, even if it would have been obvious to include a nutritive carbohydrate in the composition of YAMGATA, it would not have lead or directed a skilled person to include indigestible oligosaccharides in such a composition.

The inclusion of indigestible oligosaccharides in the present composition offers enhanced calcium uptake. This problem is neither recognized nor addressed by YAMAGATA et al. As a result, applicants request that the rejection be withdrawn.

Thus, in view of the above, applicants believe that YAMAGATA et al. fail to disclose or suggest the claimed invention.

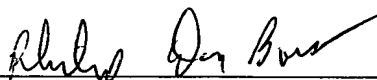
Applicants also respectfully remind the Examiner that a particular parameter or variable must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the parameter or variable might be characterized as routine or obvious. *In re Antoine*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). While the Official Action states that it would obvious to enhance the YAMAGATA et al. composition by adding oligosaccharides, incorporating proteins, and modifying the solubility of the calcium of YAMAGATA et al., the YAMAGATA et al. reference does not suggest that these parameters could be optimized or modified to obtain a recognized result. As a result, applicants believe that the Official Action fails to meet its burden in showing that one of ordinary skill in the art would optimize these claimed parameters in a manner so as to obtain the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, applicants believe that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item(s):

- Rule 1.132 Declaration of Dr. K.M.J. van Laere
- Excerpt from Advanced Dietary Fiber Technology
- MSDS of calcium gluconate